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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,856	06/27/2003	Benjamin J. Bottcher	BSCU-011/01US223C1	8238
22903	7590	12/21/2004	EXAMINER	
COOLEY GODWARD LLP ATTN: PATENT GROUP 11951 FREEDOM DRIVE, SUITE 1700 ONE FREEDOM SQUARE- RESTON TOWN CENTER RESTON, VA 20190-5061			SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 12/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/608,856	Applicant(s) BOTTCHER ET AL.	
	Examiner Bruce E Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-43 is/are pending in the application.
- 4a) Of the above claim(s) 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-37, 42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/24/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I and species 4 in the reply filed on December 03, 2004 is acknowledged. It is noted that species 4 and 5 are the same and the election of species between the two is hereby withdrawn. Claims 38-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species.

Information Disclosure Statement

The information disclosure statement filed 11/24/04, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

References A1-A359 have been considered, however, no copy of the remaining references was provided.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-37 and 42-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/032,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Both applications claim a stent comprising a first section, second section, and third section, wherein the third section is a co-extrusion of the materials used in the first and second sections. The current claims are merely broader than those in 10/032,712.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-37 and 42-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,620,202. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Both the current claims and those of said patent claim a stent comprising a first section, second section, and third section, wherein the third section is a co-extrusion of the materials used in the first and second sections. The current claims are merely broader than the patented claims.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 23, 26-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Balbierz et al (5,964,744).

Balbierz et al teaches a medical stent comprising:

a first section comprising a first material, defining a lumen, and comprising a first coil 20 completing more than one revolution, wherein the first coil revolves about and is coaxial with an axis and wherein a distance from a first point to the axis, the first point at the center of a first cross-section of the first coil and on a line normal to the axis, is less than a distance from a second point to the axis, the second point at the center of a second cross-section of the first coil and on a line normal to the axis, the first point being closer to an origin of the first coil than the second point (Note U.S. Patent 5,599,291, which is incorporated by reference teaches the retention means can be any desired shape which will provide adequate anchoring including a helical curl which fulfills the claimed configuration; see at least column 5, lines 21 et seq.);

a second section comprising a second material, defining a lumen, and comprising a second coil 24 completing at least one revolution; and

a third section defining a lumen and located between the first and second sections and adjacent the origin of the first coil, at least a portion of the third section comprising a co-extrusion of the first and second materials.

Regarding the first and second materials and their co-extrusion, Balbierz et al teaches the entire stent can be formed of a substrate layer and a coating which can be

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co-extruded therewith. See at least column 11, lines 4 et seq. The coating can be interpreted as the first material and the substrate layer can be interpreted as the second material, or vice versa. Additionally, the first and second material can be interpreted as being the same material.

Regarding at least claims 26-27, see 12:1 et seq. of 5,599,291.

Regarding the "suture", see element 33 of 5,599,291.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21, 22, 24, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz et al (5,964,744) in view of Macaluso, Jr. (5,141,502).

Balbierz et al teaches the stent as described above, however, is unclear if the second coil is generally perpendicular to the first coil or the third section generally extends along the axis. Macaluso, Jr. teaches a perpendicular configuration as shown in figure 7. It would have been obvious to one having ordinary skill in the art to have utilized the a relative perpendicular coil configuration of Macaluso, Jr. with the stent of Balbierz et al which gives better anchorage on a the coil which has its axis parallel to the third section.

Lacking any criticality in the specification, the use of EVA produces no benefit over the materials taught by Balbierz et al or Macaluso, Jr. and is considered an obvious matter of design choice.

Claim 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz et al (5,964,744) and Macaluso, Jr. (5,141,502) and further in view of Perkins et al (5,681,274).

Balbierz et al and Macaluso Jr. teach the stent as described above, however, is unclear if the first coil can be planar spiral shape. Perkins et al teaches this retention shape. Balbierz et al teaches the retention means can be any desired shape which will provide adequate anchoring. It would have been obvious to one having ordinary skill in the art to have utilized the a planar spiral coil configuration of Perkins with the stent of Balbierz et al and Macaluso Jr. because it is known in the art and would provide adequate anchoring.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

BRUCE SNOW
PRIMARY EXAMINER